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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,885	09/30/2005	Yasuo Omi	1141/75103	6799
23432 7590 10/27/2009 COOPER & DUNHAM, LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112			EXAMINER GUPTA, VANI	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 10/27/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,885	<b>Applicant(s)</b> OMI ET AL.	
	<b>Examiner</b> VANI GUPTA	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 1. Claims 1 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.***

The claim(s) contains subject matter – i.e., “calculating biological function data regarding temporal changes in values of the same pixels or sections of [a] tomogram” - which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For purposes of examination, Examiner relies on figures 13 – 16 to make an interpretation of this feature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

Claims 1 and 21 are rendered vague and indefinite because the specification of the present application does not clearly define “temporal changes in values of the same pixel or

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sections of [a] tomogram. For purposes of examination, However, for purposes of examination, Examiner relies on figures 13 – 16 for explanation of aforementioned feature, and interprets feature to mean;

- monitoring (visual) changes in the tomograms over a period of time as a result of changes in physiology and/or anatomy over time, and then coming to a conclusion about the biological function; and/or
- monitoring “pixel value changes” based on changes in intensity or brightness of images.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***1. Claims 1 – 11, 13 – 19 and 21 are rejected under 35 USC 102(e) as being anticipated by Baba et al. (WO 2004/024003).***

***Regarding Claims 1 - 21,*** Baba discloses that an image diagnostic apparatus such as an ultrasound diagnostic apparatus, a magnetic resonance imaging (MRI) apparatus, and/or an X-ray CT apparatus is capable of displaying a tomographic image of a region of an object to be examined on a monitor for conducting a diagnosis. Specifically, tomographic images can allow

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a diagnostician to diagnose the function of a variety of organs such as a circulatory organ by observing movement of the organ structure or tissue (paragraph [0002]).

Baba explains that this is generally accomplished by producing pluralities of frames of tomographic functional images of the organ under examination, and displaying this image on a display unit (paragraph [0008]). He presents an invention (fig. 1) comprising an image storing unit (#1), display unit (#2), console (#3), an automatic tracking unit (#4), and a signal line (#6), which can allow one to accurately diagnose the condition of an organ during a quantitative evaluation of its functions. This can be done by extracting an outline of a dynamic (or moving) atrium wall or ventricle wall, and superposing, overlaying, or overlapping the outline of the moving wall on the displayed image (i.e., quantitatively measuring the dynamic state of the heart tissue by displaying its movement); and calculating the volume of the ventricle from the displayed functional images (paragraph [0003] and para. [0032])).

Quantitative values such as velocity and speed of movement of the organ wall(s) can help determine the blood volume of the ventricle. This is accomplished by tracking the coordinates of the designated portion of the organ, and calculating the movement based on the coordinate information, while using the automatic tracking system. Additionally, this information can be represented by a line graph that may be displayed with the corresponding image on the monitor (paragraph [0034], last 9 lines).

Baba also explains that the designated areas of interest of the image(s) are extracted or located by setting a searchable, rectangular, area by adding pixels to the upper, lower, right, and left sides of an image (Fig. 4(b)). Any portion of an organ may be monitored. For example, it is possible to obtain a measurement of pulse wave of a large vessel wall such as a carotid artery.

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By setting a plurality of designated portions in a longitudinal direction of blood vessel wall and quantitatively measuring and comparing the moving distance of those designated portions, a degree of hardening of the arteries can be understood (paragraph [0070]).

Baba also gives examples of how the moving direction of each of designated points of an organ structure can be displayed in different colors. Additionally, a brightness modulation may be provided in accordance with the moving speed. Therefore, it is possible to grasp the movement of the cardiac muscle from a color image display (paragraph [0045]).

Baba's invention also provides a control method of region-of-interest (ROI) tracking. The console allows one inputting a command to form an ROI, while the automatic tracking unit ensures that the ROI follow the tissue movement in the moving image displayed on the display unit. The automatic tracking unit includes display control means (Fig. 15, #14) for superposing the ROI calculated based on a coordinate of its reference point after movement on another frame image in the display. A ROI-measured-information-calculating unit (fig. 15, #15) has a function that allows one to quantitatively calculating a brightness of pixel, a brightness average, a brightness shift, and so on based on the measured information such as a pixel value inside the ROI. By measuring the brightness average inside the ROI before and after movement, it is possible to accurately and quantitatively measure the blood flow in the moving cardiac muscle; and therefore, possibly, accurately and properly examine and diagnose the development and degree of a symptom or ailment (paragraph [0057 – 0069]).

Lastly, Baba discusses the possibility of applying an SAD method wherein an absolute value of a difference between corresponding pixel values of each pixel is calculated, and the sum of the absolute values is used as a correlation value; and an SSD method wherein an

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absolute value of a difference between corresponding pixel values of each pixel is calculated, and the sum of square values of the absolute values is used as a correlation value (paragraph [0073]).

With respect to “calculating at least on biological function data regarding temporal changes in values of the same pixels or section of a tomogram,” if Applicant means that there should be means for monitoring (visual) changes in the tomograms over a period of time as a result of changes in physiology and/or anatomy over time, and then coming to a conclusion about the biological function – then Baba et al. does provide teachings for this feature (see para. [0034 - 0044] and [0066 – 0073] for example). If movement of organ (movement based on physiological changes; e.g. heartbeating or breathing) is being tracked by the automatic tracking unit for sections of the image using a coordinate system (as described in para. [0039]), then “temporal changes-” i.e., changes with respect to time and space - in pixels of the images are inherently being considered. Based on this tracking, conclusions about a biological function, such as heart wall thickening, can be ascertained (para. [0044]). If Applicant means to include monitoring “pixel value changes” based on changes in intensity or brightness of images, then Baba et al. provides support for this too (para. [0066]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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**1. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baba et al. (WO 2004/024003) as applied to claim 21 above, and further in view of Kohle (US 20040096088 A1).**

*Regarding Claim 21*, Baba et al. presents the features of claim 21, as described above, for blood flow analysis for heart tissue studies.

Kohle provides teachings for monitoring temporal changes in voxels for obtaining perfusion data of brain tissue (*figs. 1 and 2, and para. [0026 – 0041]*).

It would be prima facie obvious to combine Baba et al. with Kohle to obtain additional and/or supplemental information about blood flow studies of other organs.

#### ***Response to Arguments***

**1. Applicant's arguments with respect to claims 1 – 22 have been considered but are moot in view of the new ground(s) of rejection.**

With respect to “calculating at least on biological function data regarding temporal changes in values of the same pixels or section of a tomogram,” if Applicant means that there should be means for monitoring (visual) changes in the tomograms over a period of time as a result of changes in physiology and/or anatomy over time, and then coming to a conclusion about the biological function – then Baba et al. does provide teachings for this feature (see para. [0034 - 0044] and [0066 – 0073] for example). If movement of organ (movement based on physiological changes; e.g. heartbeating or breathing) is being tracked by the automatic tracking unit for sections of the image using a coordinate system (as described in para. [0039]), then “temporal changes-” i.e., changes with respect to time and space - in pixels of the images are



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inherently being considered. Based on this tracking, conclusions about a biological function, such as heart wall thickening, can be ascertained (para. [0044]). If Applicant means to include monitoring “pixel value changes” based on changes in intensity or brightness of images, then Baba et al. provides support for this too (para. [0066]).

Applicant should note that Baba et al. (*WO 2004/024003*) claims priority to foreign applications JP 2002-266864 and 2002-267071 with filing dates September 12, 2002.

### ***Conclusion***

**1. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768